Efficient Radiology
STAIRSYSTEMS, Inc.
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5. 510(k) Summary (21 CFR 807.92(c)) K100236

ADMINISTRATIVE INFORMATION

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MAR 2 9 2010

Official Correspondent: CALISO Consulting, LLC
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Establishment Registration Number:

Date prepared: January 11, 2010

Name of Device:

Trade Name: Stair Systems Constellation

Suite

Common Name: Medical Image Workstation

Systems, PACS Classification Name: 21 CFR 892.2050

Product Code: LLZ

Identification of Predicate Device(s):

Manufacturer	Device	510(k) Number
Mercury computer Systems, Inc.	Visage PACS/CS	K062490
Ramsoft Inc.	Ramsoft PACS	K031562
Advance Imaging Solutions, LLC	EZPACS	K062878
CALGARY SCIENTIFIC, INC	ResolutionMD	K062164
Fuji Medical System USA	Fuji Synapse Workstation Software	K051553

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Intended Use Statement

The STAIR Systems PACS & DICOM Viewer Software system is a picture archiving and communications system (PACS) intended to be used as a networked Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The STAIR System PACS & DICOM Viewer Software is comprised of modular software programs that run on standard "off-the-shelf"

personal computers, business computers, and servers running standard operating systems. STAIR System & DICOM Viewer Software system is an image, data storage and display software that accepts DICOM data from any OEM modality which support DICOM standard imaging data; The system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulation, create graphical representations of anatomical areas, and perform quantitative measurements. The STAIR PACS & DICOM Viewer Software system should not be used for Diagnostic review of full-field digital mammograms.

DEVICE DESCRIPTION

STAIR Constellation Suite is a collection of applications Coded in the Microsoft C# application language. A color scheme defined as a way to identify both highlighted or important information within the user interface and as a "not so grey" environment that could stand up to a user who was likely to work 10-12 hours a day in front of it. The layout and design of the layers of the UI evolved from the "old design" of having 3 separate computers, each with a single monitor copy of a single element of the system into a modern, multi-monitor native design which incorporates large performance gains through the use of Microsoft's DirectX technologies.

The core of the Suite is the database, is an adaptive star relational design for Microsoft SQL Server 2008
Enterprise. The data server provides a dedicated, central place to provide disaster recovery servicing, and the large multi-terabyte storage required for PACS. Attaching to this are Northstar PACS clients, Cosmos Enterprise Managmenet Clients, Apex Servers, and Cascade Servers; all of which are STAIR produced software products.

The Northstar PACS client is intended to be a desktop replacement product, with the interface dominating the screen space on a workstation computer. This design decision was made to accommodate non- technical doctors who, we found, typically prefer to have a simplified and unobtrusive environment to work in. Color based exam status listings were evolutionary, and grew from the initial 'field of green' into the more advanced dynamic tree view seen today in the client. It is a multi-monitor capable client, currently configurable in a 1, 2, or 3 monitor footprint.

Cosmos represents the nerve center of the STAIR Constellation Suite, providing services for securing the STAIR network, maintaining Paperless workflow, and other such critical day-to-day system maintenance tasks. Typically users will include hospital or practice administrators and functional personnel who may need to make modifications to STAIR database entries. It is an OLTP client, and requires port level access to the main STAIR database central server installation to function (we use DSN-less connections to the

database usually requiring port 1433 to be excepted in the workstation's firewall rule set).The client performs many tasks, some of which are not relevant to every customer, though we encourage adoption of STAIR electronic processes by our clients in order to help them streamline their office efficiency. RIS integration is partially available (per vendor, STAIR offers no supported HL7 interface at this time), and can be incorporated in most cases to allow a RIS system to perform synchronization and workflow tasks in harmony with STAIR kept data records.

The Apex DICOM Storage Server provides the primary server capabilities of the STAIR system. It was built to be automatable such that it typically runs unattended, but a user interface is used to both help monitor and control the various DICOM storage processes necessary to import each study from an external source (modality, another PACS, etc). The Apex server incorporates a DICOM SCP service grouping that allows for DICOM ping response, client protocol negotiation, transfer syntax negotiation, and several other system-level DICOM negotiations. As each case is received; it is stored via a Service host to the local hard drive (into the STAIRIMAGE hierarchy), it is queued for storage at the top, and it is stored as data to the main database in one of 8 available simultaneous thread 'put-away' processes (shown as 'idle').

The STAIR Cascade is a DICOM SCU, and auxiliary compression Server product originally designed to allow the send and receive functions of DICOM to be split from the STAIR Apex product and balanced onto a separate physical server. This was to allow for load balancing within the STAIR Enterprise, and the product has evolved now into a secondary server role, handling transmission queues for all enterprise clients. To allow for DICOM transmissions to be seamless, we use a database table XMISSION_QUES, and each client transmission request to the database are handled as a threaded process (8 simultaneous). Each process begins by downloading the Imageset for a requested case from the STAIR database to a local cache, where it is then added to a queue within the program for processing. As each queue slot opens, another case is promoted until the queue empties.

Predicate Device Comparison

The Stair Systems Constellation Suite has similar intended use and technical features of the predicate devices listed above. The subject device is not indicated for Mammography use where as some of the predicate devices are indicated. This difference in the subject device does not raise any questions with respect to the safety and effectiveness of the device. substantially equivalent to similar features to the predicate devices. The Stair Systems Constellation Suite differs from the Fuji Medical Synapse in that it is not intended for Mammography use. The features of the subject device do not raise or affective the safety or effectiveness of the device.

The subject device does comply with the following voluntary Standards:

- ACR/NEMA Digital Imaging and Communication in Medicine (DICOM) Standard.

Conclusions

A comparison of the labelling, substantial equivalence table, and verification and validation testing has established that the device meets its intended use and design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

STAIRS Systems, Inc.
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Regulatory Affairs
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GREENSBORO NC 27407

MAR 2 9 2010

Re: K100236
Trade/Device Name: Stair Systems Constellation Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2010
Received: February 2, 2010

Dear Mr. Monroe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

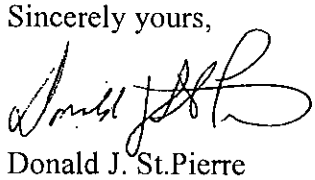
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
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Enclosure

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Indications for Use

510(k) Number (if known): K100236

Device Name: Stair Systems Constellation Suite

Indications for Use:

The Stair Systems Constellation Suite Software system is a picture archiving and communications system (PACS) intended to be used as a networked Digital Imaging and Communications in Medicine (DICOM) and non- DICOM information and data management system. The STAIR System PACS & DICOM Viewer Software is comprised of modular software programs that run on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems. STAIR System & DICOM Viewer Software system is an image, data storage and display software that accepts DICOM data from any OEM modality which support DICOM standard imaging data; The system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulation, create graphical representations of anatomical areas, and perform quantitative measurements.

The STAIR Systems Constellation Suite Software system should not be used for Diagnostic review of full-field digital mammograms.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100236